NOT FOR PUBLICATION (Doc. No. 30)

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

BRITTANI TIGERT,	:	
Plaintiff,	:	Civil No. 12-00154 (RBK/JS)
v.	:	**OPINION**
RANBAXY PHARMACEUTICALS, INC et. al.,	:	
Defendants.	:	

KUGLER, United States District Judge:

This matter comes before the Court on the motion of Medicis Pharmaceutical Corporation ("Defendant") for judgment on the Second Amended Complaint of Brittani Tigert ("Plaintiff'), pursuant to Federal Rule of Civil Procedure 12(c). Plaintiff allegedly suffered serious liver damage after taking the prescription drug Solodyn®. Plaintiff now contends that Defendant failed to adequately warn consumers of Solodyn's dangers, seeking damages under either a strict products liability or negligence theory of liability. Defendant asserts its presumptive non-liability under Texas law, which undisputedly applies to this case. Defendant further notes that both the Fifth Circuit Court of Appeals and several Texas district courts have held that the immunity exception Plaintiff seeks to invoke is preempted by federal law. Despite Defendant's request that the Court defer to the Fifth Circuit's ruling, the Court finds that the

presumption against preemption obtains in this case. Accordingly, Defendant's motion for judgment on the pleadings is **DENIED.**

I. BACKGROUND

Plaintiff, a 21 year old college student, was prescribed Solodyn® ("Solodyn") to treat her acne. Compl. ¶7.3. Defendant manufactures, markets, and distributes Solodyn. Id. at ¶6.3. After allegedly filling six prescriptions for the drug, Plaintiff suffered serious liver damage and experienced liver failure. Id. at ¶7.5. Plaintiff claims that when she was originally prescribed Solodyn, the drug's packaging insert "grossly understated the risks associated" with Solodyn. Id. at ¶8.6. The actual label on the drug, however, was approved by the Food and Drug Administration ("FDA") and featured FDA-approved warnings. See Id. at ¶8.6. Plaintiff continues to receive treatment for her condition and claims that her use of Solodyn caused permanent injuries. Id. at ¶7.4.

Plaintiff now seeks damages, under either strict products liability or a negligence theory of liability, for Defendant's alleged failure to warn consumers and medical care professionals of the potential dangers of Solodyn. Plaintiff initially also brought common law claims for misrepresentation of facts, breach of implied warranty, and fraudulent concealment, but later stipulated to their dismissal.

Defendant files the present motion asserting its immunity as a matter of law. Under Texas law, defendants in "failure to warn" products liability actions are afforded a rebuttable presumption of non-liability when "the warnings or information that accompanied the product in its distribution were those approved by the United States Food and Drug Administration." Tex. Civ. Prac. & Rem. Code §82.007(a)(1). This presumption may be rebutted by establishing that "the defendant, before or after pre-market approval. . .withheld from or misrepresented to the

United States Food and Drug Administration required information that was material and relevant to the performance of the product and was causally related to the claimant's injury." §82.007(b)(1). Defendants raise §82.007(a)(1) as an affirmative defense and contend that the §82.007(b)(1) exception is preempted by federal law according to the Supreme Court's decision in Buckman Co. v Plaintiff's Legal Comm., 531 U.S. 341 (2001). Plaintiff urges this Court to adopt an alternative interpretation of both the Texas statute and recent case law and find no preemption.

II. LEGAL STANDARD

Under Fed. R. Civ. P. 12(c), a court will grant judgment on the pleadings if, on the basis of the pleadings, no material issue of fact remains and the movant is entitled to judgment as a matter of law. See Fed. R. Civ. P. 12(c); DiCarlo v. St. Mary Hosp., 530 F.3d 255, 259 (3d Cir. 2008). In reviewing 12(c) motions, the court must accept the nonmoving party's well-pleaded factual allegations as true and construe those allegations in the light most favorable to the nonmoving party. See DiCarlo, at 262-63. The court "may grant such a motion only where 'it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief.'" Carino v. Stefan, 376 F.3d 156, 159 (3d Cir. 2004) (quoting Conley v. Gibson, 355 U.S. 41, 45-46 (1957)).

III. DISCUSSION

Plaintiff's ability to overcome Defendants' presumptive non-liability hinges on whether this Court will follow the Fifth Circuit decision in Lofton v. McNiel Consumer & Specialty Pharmaceuticals that §82.007(b)(1) is preempted, or adopt the position of the Second Circuit and

determine that it is not.[1] See Lofton, 672 F.3d 372 (5th Cir. 2012); see Desiano v. Warner-Lambert & Co., 467 F.3d 85 (2d Cir. 2006). Defendant encourages the Court to defer to the Fifth Circuit's interpretation of Buckman, citing the general principle that, where possible, courts should interpret the law to avoid circuit conflicts. See Def.'s Reply Br. Further Supp. Mot. J. Pleadings ("Def.'s Reply Br.") at 3-4. Defendant further notes that the Court should defer to the Fifth Circuit because it is the regional circuit court. Id. at 4.

As a preliminary matter, this Court is not bound by the Fifth Circuit's interpretation of federal law. See e.g. Desiano, 467 F.3d at 90-91 (stating the court was not obligated to defer to a foreign circuit's views on federal law); see also Colby v. J.C. Penny Co., Inc., 811 F.2d 1119, 1123 (7th Cir. 1987) (noting that neither circuit nor district courts are required to give automatic deference to the decisions of other courts of appeals). Moreover, whatever duty the Court may have had to avoid a circuit conflict is now irrelevant, as a split of authority already exists among courts who have addressed this issue. See Garcia v. Wyeth-Ayerst Labs., 385 F.3d 961 (6th Cir. 2004) (holding that Michigan statute containing an immunity exception was preempted by federal law); accord Lofton, 672 F.3d at 381 (§82.007(b)(1) preempted by federal law absent the FDA's prior finding of fraud). But see Desiano, 467 F.3d at 98 (concluding that the Michigan immunity exception is not prohibited through preemption); accord Yocham v. Novarties Pharmaceuticals Corp., 736 F.Supp.2d 875 (D.N.J. 2010) (holding that §82.007(b)(1) not preempted by federal law). Therefore, this Court will evaluate the question of federal preemption independently, declining to automatically defer to the Fifth Circuit's interpretation.

[1] Neither party challenges the applicability of Texas law to this dispute. See Pl. Second Amend. Compl. at 18; Def.'s Mot. J. Pleadings at 1. As such, a choice of law analysis is unnecessary.

The Lofton Decision

The Fifth Circuit faced a substantially similar question to the one now before this Court in Lofton. The plaintiffs sued a drug manufacturer for the manufacturer's alleged failure to warn consumers of the risk of severe autoimmune allergic reactions to Motrin®. Lofton, 672 F.3d at 374. The drug manufacturer moved for summary judgment, asserting the Texas presumption of non-liability. Id. The plaintiffs attempted to overcome the presumption by arguing, pursuant to §82.007(b)(1), that the drug manufacturer had withheld or misrepresented material information to the FDA, but the district court found that federal law preempted the state statute. Id. at 375. On appeal, the Fifth Circuit affirmed the district court's ruling. Id. at 381.

In the absence of directly on point precedent from either the United States or Texas Supreme Court, the Fifth Circuit searched for guidance in relevant Supreme Court decisions and the conflicting decisions of two circuit courts. At the time, the Supreme Court had held that traditional products liability claims were not preempted merely because a drug's warning label was approved by the FDA, See Wyeth v. Levine, 555 U.S. 555 (2009), but that fraud on the agency claims, in which liability attached "solely by virtue of the FDCA disclosure requirements," were preempted by federal law. See Buckman Co. v Plaintiff's Legal Comm., 531 U.S. 341 (2001). The Lofton court first questioned whether the Texas statute fit more appropriately within the Buckman framework or was shielded from preemption altogether under Wyeth. Lofton, 672 F.3d 375-77. After deciding that the Buckman framework applied, the court then evaluated competing interpretations of the Supreme Court's decision. Id. at 377.

Both the Second and Sixth Circuit had encountered the question of Buckman preemption with a similar Michigan immunity exception[2] and reached divergent conclusions. The Sixth

2 The Michigan statute stated in relevant part:

Circuit determined that the exception was impliedly preempted by Buckman, because the statute "inevitably conflict[ed] with the FDA's responsibility to police fraud consistently with the Agency's judgment and objectives." Garcia, 385 F.3d at 965 (quoting Buckman, 531 U.S. at 350). Noting the applicability of concerns about judicial interference with the FDA cited in Buckman, the Sixth Circuit found that the Michigan statute was not sufficiently distinct from a fraud on the agency claim to merit differential treatment. Id. at 965-66. Consequently, the court held that unless the FDA itself had already found fraud, plaintiffs could not attempt to overcome the presumption of non-liability by invoking the "fraud-on-the-FDA" statutory exception. Id. at 967.

The Second Circuit, however, subscribed to a narrower interpretation of Buckman, holding that the Michigan statute was not preempted. See Desiano, 467 F.3d at 98. The court first found that the "presumption against preemption," which did not apply in Buckman, attached to the plaintiff's claims because they fell within the legislature's power to regulate matters of health and safety, "a sphere in which the presumption against preemption. . . stands at its strongest." Id. at 94. The court also noted that the plaintiffs were not pursuing "fraud-on-the-FDA" claims, but rather were "asserting claims that sound in traditional state tort law."[3] Id. The court further

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"(5) In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller. . . This subsection does not apply if the defendant at any time before the event that allegedly caused the injury does any of the following:

(a) Intentionally withholds from or misrepresents to the United States food and drug administration information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act, and the drug would not have been approved, or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted." Mich. Comp. Laws Ann. § 600.2946 (5)(citations omitted).

[3] The Second Circuit also importantly noted that the position of no preemption aligned with the pharmaceutical industries' position articulated during oral argument in Buckman. The pharmaceutical industry stressed the unusual

distinguished the matter before them from Buckman because proof of fraud against the FDA was not an actual element of the plaintiffs claim, but rather would become germane "only if a defendant company chooses to assert an affirmative defense made available by the Michigan legislature."[4] Id. at 96 (emphasis in original). Noting that "common law liability cannot be easily displaced in our federal system," the court found that the Michigan statute did not "implicate the same concerns that animated the Supreme Court's decision in Buckman" and was consequently not preempted. Id. at 97.

The Fifth Circuit evaluated each court's rationale and found the Second Circuit's interpretation unpersuasive. See Lofton, 672 F.3d at 379. Skirting the question of whether the presumption against preemption applied, the court reached the conclusion that "because §82.007(b)(1) requires a Texas plaintiff to prove fraud-on-the-FDA to recover for failure to warn, this requirement invokes federal law supremacy according to Buckman." Id. The court rejected the Second Circuit's distinction between fraud on the agency as a predicate to recovery and the fraud on the agency cause of action, asserting that the distinction fails "when the statute at issue conditions recovery on 'establishing' what amounts to fraud on the agency." Id. at 380. The court adopted the Sixth Circuit's ruling on this basis, finding that "the threat of imposing state liability on a drug manufacturer for defrauding the FDA intrude[d] on the competency of the FDA and its relationship with regulated entities." Id.

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nature of the claims asserted by the plaintiffs and stated that "this is a very unusual form of State law product liability action. The plaintiffs don't claim that these devices were in any way defective. There's no claim here of manufacturing defect. There's no claim here of design defect. The plaintiffs also don't claim that the surgeon who used these devices did anything wrong. There's no claim of medical malpractice." Desiano, 467 F.3d at 95 (quoting Oral Argument Transcript, Buckman, 531 U.S. 341 (2000)(No. 98-1768)).

[4] The Court is not persuaded by this argument or by the Second Circuit's assertion that "only when proof of fraud is by itself sufficient to impose liability-and indeed is the sole basis of liability (as it was in Buckman)-does the incentive to flood the FDA appreciably escalate." Desiano, 467 F.3d at 97 (emphasis in original). This is a "distinction without a difference." Yocham, 736 F.Supp.2d at 888. As a practical matter, the concerns of flooding the FDA remain whether fraud on the agency is an essential element of the plaintiff's claim, or a procedural hurdle to overcome the presumption of non-liability. Nevertheless, the Court finds that the statute is not preempted.

Reconsidering Lofton

The Fifth Circuit emphasized the dangers recognized in Buckman and their potential realization if plaintiffs were permitted to invoke §82.007(b)(1) to overcome defendants' presumptive non-liability. Unfortunately, the court highlighted certain portions of the Buckman opinion to the exclusion of others. The Supreme Court indeed cautioned that state law fraud-on-the-agency claims incentivized applicants "to submit a deluge of information that the Administration neither wants nor needs, resulting in additional burdens on the FDA's evaluation of an application." Buckman, 531 U.S. at 351. This was not, however, the primary rationale motivating the decision.

The Supreme Court reached concerns of burdening the FDA only after determining that the presumption against preemption did not obtain in Buckman. The court contrasted fraud on the agency claims, which existed "solely by virtue of the FDCA disclosure requirements," from traditional state tort law claims, which implicated "federalism concerns and the historic primacy of state regulation of matters of health and public safety." Id. at 347-48, 353. The court further distinguished the claims in Buckman from traditional state tort law claims by noting that fraud on the agency claims served solely as a mechanism for policing the FDA. This mechanism was not only duplicative, as the FDA "has at its disposal a variety of enforcement options that allow it to make a measured response to suspected fraud upon the Administration," but also potentially troublesome as it could impose "additional burdens" on the FDA. See Id. at 349-51. This distinction is crucial because unlike traditional state tort law claims in which the plaintiffs must still establish the elements of a tort, thus regulating the interaction between the defendant and plaintiff, fraud on the agency claims regulated only the "defendant's interaction with a federal agency." Yocham, 736 F.Supp.2d at 887. The Fifth Circuit overlooked these critical differences

when it failed to recognize the applicability of the presumption against preemption and expanded Buckman preemption to §82.007(b)(1).

While this Court finds persuasive Defendant's argument that similar concerns of judicial oversight of the FDA manifest with §82.007(b)(1), these concerns were not the decisive factors in the Supreme Court preempting fraud on the agency claims. The court reached concerns of interference only after first finding that fraud on the agency claims presented a unique circumstance in which the traditional presumption against preemption of state law did not apply. Such is not the case here. As such, the Supreme Court's narrow ruling in Buckman is unstable ground on which to rest a finding of preemption. Therefore, the Court finds that §82.007(b)(1) is not preempted by federal law.

Sufficiency of Plaintiff's Second Amended Complaint

Defendant alternatively argues that if the Court declines to follow Lofton, the Court must still grant the motion for judgment on the pleadings because Plaintiff does not allege fraud with sufficient particularity pursuant to Federal Rule of Civil Procedure 9(b).[5] Fed. R. Civ. Proc. R. 9(b) (2006). This argument was raised for the first time in Defendant's reply brief. In both the Answer and brief in support of the motion for judgment on the pleadings, Defendant contends that Plaintiff failed to allege fraud with particularity only with respect to the misrepresentation, breach of implied warranty, and fraudulent concealment claims, all of which were voluntarily dismissed. See Def.'s Answer ¶¶ 10.1-12.10; see also Def.'s Mot. J. Pleadings at 12. Consequently, the Court will decline to consider this argument. See U.S. v. Boggi, 74 F.3d 470, 478 (3d Cir. 1996) (Court of appeal would not consider arguments raised in a reply brief so that

[5] Defendant also implies, without any supporting law, that Plaintiff's stipulation to dismissal of the misrepresentation and fraudulent concealment claims precludes her from invoking the statutory exceptions to Defendant's presumptive non-liability. The Court finds this argument unpersuasive.

appellees are not prejudiced by the lack of opportunity to respond); see also Stern v. Halligan, 158 F.3d 729, 731 n.3 (3d Cir. 1998) ("A party cannot raise issues for the first time in a reply brief."); see also D'alessandro v. Bugler Tobacco Co., 2007 WL 130798 (D.N.J. Jan. 12, 2007) (stating that a moving party may not raise new issues in a reply brief because "no sur-reply is permitted, so the opponent has no opportunity to address the new defense.")

IV. CONCLUSION

For the foregoing reasons, Defendant's motion for judgment on the pleadings pursuant to Federal Rule of Civil Procedure 12(c), is DENIED. An accompanying order shall issue today.

Dated: 12/18/2012

/s/ Robert B. Kugler
ROBERT B. KUGLER
United States District Judge